WSA 2004 Proposed Project

Project Name:	Early Biomarkers of Inflammation in CVD (N01466)
Purpose:	The *primary objective* is the identification of differentially expressed RNA transcripts transcribed from genes in circulating cells present in venous blood and small proteins present in plasma obtained thereof that are up- or down regulated in active cigarette smokers compared to healthy nonsmokers with the aim to detect new endogenous biomarkers of inflammation in smokers predictive for atherosclerotic and other inflammatory diseases. *Secondary objectives* are the validation of known cell surface receptors as cellular biomarkers by flow cytometry testing in smokers and nonsmokers and the validation of known biomarkers of cigarette smoking in plasma (i.e., fibrinogen, leukocytes etc).

Reason for Doing this Work:

- ☐ Guidance
- ☒ Evaluation
- ☐ Product Design
- ☐ Short Term
- ☒ Long Term

Initiative and sub-initiative: (Check all areas that apply)

- ☐ Determinants of Exposure
  - ☐ Addiction
  - ☐ Ammonia
- ☐ Understanding Product Toxicity vs Product Design
  - ☐ Exposure
  - ☐ Carbon
  - ☐ Menthol
  - ☐ Low Tar
  - ☐ ETS
  - ☐ Specific Compounds
- ☒ Evaluation Framework Clinical
  - ☐ Cancer
  - ☐ COPD
  - ☒ CVD
  - ☐ Molecular Biology
  - ☐ All Disease
- ☐ Evaluation Framework Non-Clinical
  - ☐ Cancer
  - ☐ COPD
  - ☐ CVD
  - ☐ Molecular Biology
  - ☐ All Disease
- ☐ Broaden Flexibility after Clinical Studies
- ☐ Rapid Screening
- ☐ Knowledge Management
- ☐ Risk Assessment
- ☐ Communication
- ☐ Surveillance
- ☐ Smoking Conditions
- ☐ Improve Prep Subjectives
- ☐ Lit End Cigarette Reduced Exposure Design

Project Leader: Martin Unverdorben

Functional Area: Clinical Evaluation

Prioritization: ☒ Critical ☐ Priority ☐ Secondary ☐ Low

Milestones:	Target Start Date	Previous Completion Date	Target Completion Date:
Discuss study with investigator	01/01/03	2/28/03	04/28/03
Final protocol	01/01/03	3/31/03	01/31/04
Contract	01/01/03	06/15/03	02/29/04
Preparation of clinical conduct	03/01/04	09/30/03	06/30/04
Study conduct Period (screening and visit 1	07/01/04	03/30/05	07/31/05
Data cleaning (clinical), data base closure (clinical), data cleaning (laboratory) Period 1	08/01/05	04/30/05	08/31/05
Data analysis Period 1	09/01/05	07/01/05	10/31/05
Period 1 report	11/01/05	09/15/03	02/28/06
18-month follow-up (Period 2)	06/01/06	05/31/06	12/31/06
Data cleaning and analysis Period 2	01/01/07	11/30/06	04/30/07
Report Period 2	05/01/07	02/28/07	06/30/07
Three year follow-up (Period 3)	07/01/07	11/30/07	06/30/08
Data cleaning and analysis Period 3	07/01/08	06/30/08	11/30/08
Finals Report (Periods 1 thru 3)	12/01/08	11/30/08	02/29/09

Internal Resource Allocation (WSA, PMRL, PMI) (Man Hours)	External Resource Allocation (other PMUSA, external vendors) (Man Hours)
M.Unverdorben 680 300	1,375

TO BE FILLED OUT BY WSA MANAGEMENT

Signature of Project Leader's Functional Director (Date)

- ☐ Approved as Written
- ☐ Approved as Written
- ☐ Approved with Modifications
- ☐ Not Approved

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Source: https://www.industrydocuments.ucsf.edu/docs/snlj0001